



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2017

Bracco Injeneering S.A.
% Mr. Thomas Kroenke
Speed to Market, Inc
P.O. Box 3018
Nederland, Colorado, 80466

Re: K133147

Trade/Device Name: Bracco Injeneering Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name:
Regulatory Class: II
Product Code: PQH
Dated: June 13, 2014
Received: June 16, 2014

Dear Mr. Thomas Kroenke:

This letter corrects our substantially equivalent letter of June 20, 2014

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Michael J. Ryan -S

for Lori A. Wiggins, MPT, CLT
Acting Division Director
Science and Policy
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number (if known)
K133147

Device Name
Bracco Injengineering Transfer Set

Indications for Use (Describe)

The Bracco Injengineering Transfer Set is a component of a contrast management system and is indicated for the transfer of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours has elapsed since the container was penetrated, whichever occurs first.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



Digitally signed by Richard C.
Chapman -S
Date: 2014.06.20 12:18:43 -04'00'

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JUN 20 2014

510(k) Summary

K133147

Submission Date: 18 June 2014

Submitter: Bracco Injeneering S.A. (formerly Swiss Medical Care)
Avenue de Sévelin 46
1004 Lausanne
Switzerland

Submitter Contact: Mr. Marc Gingins
Phone: +011 41 21 621 74 00
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Email: marc.gingins@bracco.com

Trade Name: Bracco Injeneering Transfer Set

Common Name: Intravascular Administration Set

Classification Name: Intravascular Administration Set

Classification Regulation: 21 CFR §880.5440

Product Code: FPK

Substantially Equivalent Devices:	BINJ Model	Predicate 510(k) Number	Predicate Manufacturer and Model
	BINJ Transfer Set	K041178	E-Z-EM, Inc. (now ACIST Medical Systems, Inc.) Empower Transfer Set

Device Description: The Bracco Injeneering (BINJ) Transfer Set is a sterile tubing set for connection between an imaging bulk package and empty sterile syringes on single-use-only, syringe based contrast delivery systems (injectors). The BINJ Transfer Set is approximately 20 inches long, and its components are made with medical grade materials.

The BINJ Transfer Set is supplied ethylene oxide (EtO) sterilized to a Sterility Assurance Level (SAL) of 10^{-6} , and is individually packaged. At the time of this submission, accelerated aging tests confirm a one (1) year shelf life. The BINJ Transfer Set is disposable, and is to be discarded after the contrast media container has been depleted, or 10 hours has elapsed since the container was spiked.

Intended Use: The transfer set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast delivery systems (injectors).

Indications for Use The Bracco Injeneering Transfer Set is a component of a contrast management system and is indicated for the transfer of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours has elapsed since the container was penetrated, whichever occurs first.

Technology Comparison: The BINJ Transfer Set employs the same technological characteristics as the predicate device.

Characteristic Comparisons:

Intended Use

Indications for Use

Tubing Length, Nominal

Sterility Method

Sterility Assurance Level

Disposable or Reusable

<i>E-Z-EM, Inc. (ACIST Medical Systems, Inc.) Empower Transfer Set (K041178)</i>	<i>Bracco Injeneering S.A. BINJ Transfer Set</i>
The transfer set is intended for the transfer of fluids from bulk containers to empty sterile syringes on syringe based contrast delivery systems (injectors).	Same.
The Empower Transfer Set is intended to deliver fluid (contrast media or saline) from a container into a CT power Injector syringe.	The Bracco Injeneering Transfer Set is a component of a contrast management system and is indicated for the transfer of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package to empty sterile syringes on single-use only syringe-based contrast injection systems indicated for the controlled, automatic administration on the venous side, of contrast agents for CT procedures. The Transfer Set is to be discarded after the contrast media container has been depleted or 10 hours has elapsed since the container was penetrated, whichever occurs first.
6 "	20 "
Ethylene Oxide (EtO)	Same
10 ⁻⁶	Same
Disposable	Disposable after the contrast media container has been depleted, or 10 hours has elapsed since the container was spiked.

Packaging

Individually packaged in a Tyvek pouch

Individually packaged in a 6" x 10" white Tyvek and clear polyethylene pouch.

Shelf-Life

One (1) year

Same

Performance Testing:

Sterilization

The BINJ Transfer Set is ethylene oxide (EtO) sterilized and was validated to a sterility assurance level of 10^{-6} in accordance with the following standard prior to commercial distribution:

- *ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Verification results indicate that the BINJ Transfer Set complies with the standard.

Shelf-Life

The BINJ Transfer Set is sterilized and its packaging was validated in accordance with the following standards:

- *ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems; and*
- *ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

Verification results indicate that the BINJ Transfer Set complies with the standards.

Biocompatibility

BINJ Transfer Set indirect patient contact materials were verified in accordance with the following standard:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicated that the materials comply with the standard.

***Performance Testing
– Bench***

The BINJ Transfer Set was tested for performance in accordance with its predetermined specifications as specified in *Section 11, Device Description – Performance Specifications*, of this submission, and verified in accordance with the following standards:

- *IEC 62366: 2007, Medical devices – Application of usability engineering to medical devices*
- *ISO 594-2: 1998, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*
- *ISO 8536-4: 2010, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed.*

Specific, predetermined specifications testing of note included:

- *Microbial ingress testing; and*
- *Chemical compatibility, leachable compounds and particulates testing.*

Test and verification results indicate that the BINJ Transfer Set complies with its predetermined specifications and the standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the BINJ Transfer Set. The results of these activities demonstrate that the BINJ Transfer Set is safe and effective when used in accordance with its intended use and labeling.

Therefore, the BINJ Transfer Set is considered substantially equivalent to the predicate device.